Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12516. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for an enzyme immunoassay to be used as an aid in the diagnosis of patients with transitional cell carcinoma of the urinary tract.

Procedure: On December 13, 1999, from 10 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 1, 1999. On December 13, 1999, oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:15 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 1, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On December 13, 1999, from 9:30 a.m. to 10 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device submissions (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this information.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 17, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–30704 Filed 11–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 16, 1999, 8:30 a.m. to 5 p.m.

Location: DoubleTree Hotel, Plaza Ballroom, 1750 Rockville Pike, Rockville, MD.

Contact Person: Robert J. Doyle, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd. Rockville, MD 20850, 301–594–1212, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12526. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a digital mammography device.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 8, 1999. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. Near the end of the committee deliberations, a 30 minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 8, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 15, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–30705 Filed 11–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4577]

Draft ''Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing a draft guidance document entitled ''Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma.'' The purpose of the draft guidance document is to seek public comment on FDA's approach to regulating nucleic acid testing for infectious agents when intended for use in blood donor screening and/or manufacturing of blood products. FDA is issuing the draft guidance document in response to requests from manufacturers for guidance in the development of nucleic acid testing of plasma pools for infectious agents.

DATES: Written comments may be submitted at any time, however, comments should be submitted by January 25, 2000, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at